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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,757	04/20/2006	Heike Sederoff	JIB-1571	9030

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,757	SEDEROFF ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20080627*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of the invention of Group I, claims 1-16, in the reply filed on May 6, 2009 is acknowledged. The traversal is on the ground(s) that the inventions relate to a single inventive concept, namely related peptides that block actin depolymerization through an F-actin-related mechanism. This is not found persuasive because the invention of Group II is not drawn to peptides, but rather is drawn to polynucleotides. Peptides and polynucleotides do not have a common property or activity, and do not share any significant structural elements. Note that multiple claimed products do not necessarily possess unity of invention. See 37 CFR 1.475(c) and (d).

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 6, 2009.

Applicant's election of the species SEQ ID NO:12 in the reply filed on August 13, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

SEQ ID NOS:1, 3, and 11 as set forth in Figure 1A do not correspond with SEQ ID NOS:1, 3, and 11 as defined in the Sequence Listing filed June 16, 2008.

SEQ ID NO:23 as set forth in Figure 1B does not correspond with SEQ ID NO:23 as defined in the Sequence Listing filed June 16, 2008.

SEQ ID NOS:2-4 as set forth at page 3, paragraph [011], of the specification do not correspond with SEQ ID NOS:2-4 as defined in the Sequence Listing filed June 16, 2008.

Amino acid sequences subject to the sequence disclosure rules are present, e.g., in paragraphs [013], [049], [056], [057], and [088]; in the last line of Table 1 (i.e. the consensus sequence); and in claims 5, 6, 10, 13, and 14; but are not listed in the Sequence Listing filed June 16, 2008.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

The computer readable form of the Sequence Listing filed June 16, 2008 was approved by STIC for matters of form.

3. The drawings are objected to because:

(A) It appears that Figures 3 and 6 are intended to be color drawings. See, e.g., paragraphs [026], [029], [030], and [096].

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and,

unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

(B) Paragraphs [026] and [027] of the specification refer to Fig. 3A through 3F, and to Fig. 4A through 4F. However, the subpart labels, i.e. A, B, C, D, E, and F, are illegible in the figures.

(C) SEQ ID NOS:1, 3, and 11 as set forth in Figure 1A do not correspond with SEQ ID NOS:1, 3, and 11 as defined in the Sequence Listing filed June 16, 2008. SEQ ID NO:23 as set forth in Figure 1B does not correspond with SEQ ID NO:23 as defined in the Sequence Listing filed June 16, 2008.

(D) The meaning of the three superscript "^{N}" in Figure 1A, SEQ ID NO:18, is not known, and does not appear to be explained in the specification. If these were intended to stand for asparagine residues, revision of the sequence listing will be necessary.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The disclosure is objected to because of the following informalities: SEQ ID NOS:2-4 as set forth at page 3, paragraph [011], of the specification do not correspond with SEQ ID NOS:2-4 as defined in the Sequence Listing filed June 16, 2008. SEQ ID NOS must be inserted after all amino acid sequences subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such amino acid sequences are present, e.g., in paragraphs [013], [049], [056], [057], and [088], and in the last line of Table 1 (i.e. the consensus sequence). At page 16, line 4, it is believed that "slowing" should be changed to "slowly". Paragraph [0114] refers to "Fig. 68B"; however, it is believed that this should read "Fig. 6B". Paragraph [0117] refers to "Fig. 8E"; however, it is believed that this should read "Fig. 6E". Paragraph [0117] refers to "Fig. 8F"; however, it is believed that this should read "Fig. 6F". Appropriate correction is required.

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims appear to embrace naturally occurring proteins, in particular sucrose synthases isolated from Zea mays. See, e.g., [010] and Table 1 of Applicants' specification. Products of nature do not constitute patentable subject matter. Note the lack of

any limitation such as "isolated" and "purified" in Applicants' claims. Further, as described in paragraph [008] of Applicants' specification, sucrose synthases occur naturally in cells, and appear to associate with actin in situ. Applicants' method claims appear to describe a naturally occurring method involving sucrose synthases, and therefore do not constitute patentable subject matter. Note that the method claims lack, e.g., any limitation as to the type of cell which must be contacted with the peptides.

6. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the addition" at claim 10, line 17. Alternatively, it is not clear to what the compound/peptide is being added. There is no antecedent basis in the claim for the phrase "said compound" at claim 10, line 17.

7. Claims 2, 5-10, and 12-16 are objected to because of the following informalities: At claim 2, line 10, and claim 12, line 11, "X2" should be changed to "X_2". At claim 2, line 12, and claim 12, line 13, the reference to "as set forth in Figure 1B" is redundant to the immediately preceding line, which explicitly recites the amino acid sequence giving the respective positions. The reference to the Figure should be deleted from the claims. SEQ ID NOS must be inserted after all amino acid sequences subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such sequences are present in claims 5, 6, 10, 13, and 14. At claim 14, line 1, "comprising" should be changed to "comprises". Appropriate correction is required.

8. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claim 14 recites a generic peptide sequence, and claim 15, which depends upon claim 14, recites specific peptide sequences, including SEQ ID NO:12. However, SEQ ID NO:12 is not a species of the generic peptide sequence of claim 14, because SEQ ID NO:12 lacks the N-terminal EH* residues required by the generic peptide formula. Accordingly, claim 15 embraces subject matter not embraced by claim 14, upon which claim 15 depends, and claim 15 is an improper dependent claim.

9. Applicant is advised that should claim 1 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 1 is drawn to a "peptide", which is defined in paragraph [031] of the specification as an amino acid sequence between 2 and 100 amino acids in length. Accordingly, dependent claim 3 recites a characteristic which is inherently present in the subject matter of independent claim 1, and therefore claim 3 is identical in scope with claim 1.

10. The attempt to incorporate subject matter into this application by reference to GenBank Accession Number 1498382 (see, e.g., paragraph [014] of the specification) is ineffective because the subject matter sought to be incorporated is essential subject matter, as evidenced by its recitation in claim 4. However, it is improper to incorporate essential subject matter by reference to a non-U.S. patent.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any

outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

It should be noted that should the correction involve inserting a new sequence subject to the sequence disclosure rules into the specification, the sequence listing will have to be revised to list the newly recited sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The protein sequence set forth in GenBank Accession Number 1498382 is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The protein sequence is explicitly referred to in claim 4, and is necessary in order to determine homology of peptides which might be embraced within the scope of the claim. However, incorporation by reference to a non-U.S. patent in order to define the protein sequence is not permitted under 37

CFR 1.57, and therefore the specification does not enable one skilled in the art to use the protein sequence in order to identify and describe the claimed peptides.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-10 are rejected under 35 U.S.C. 102(a) and/or (e) as being anticipated by Liu et al (U.S. Patent Application Publication 2003/0034888). Liu et al teach a polypeptide identified as SEQ ID NO:54668 and having the following sequence:

```
SEQ ID NO 54688
LENGTH: 97
TYPE: PRT
ORGANISM: Glycine max
FEATURE:
OTHER INFORMATION: Clone ID: 700832792_FLI.pep
SEQUENCE: 54688
    Val Phe Gly Thr Glu His Ser His Ile Leu Arg Val Pro Phe Arg Thr
      1               5                  10                  15
    Glu Lys Gly Ile Val Arg Lys Trp Ile Ser Arg Phe Glu Val Trp Pro
                 20                  25                  30
    Tyr Leu Glu Thr Tyr Thr Glu Asp Val Ala His Glu Leu Ala Lys Glu
             35                  40                  45
    Leu Gln Gly Lys Pro Asp Leu Ile Val Gly Asn Tyr Ser Asp Gly Asn
         50                  55                  60
    Ile Val Ala Ser Leu Leu Ala His Lys Leu Gly Val Thr Gln Cys Thr
     65                  70                  75                  80
    Ile Ala His Ala Leu Glu Lys Thr Lys Tyr Pro Glu Ser Asp Ile Tyr
                     85                  90                  95
    Trp
```

Residues 19-34 of Liu et al's polypeptide correspond to Applicants' SEQ ID NO:12, and residues 26-31 correspond to Applicants' SQ ID NO:22. In view of the similarity in amino acid sequence between Liu et al's polypeptide and Applicants' claimed peptide, inherently Liu et al's polypeptide will bundle actin and inhibit actin depolymerization to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between Liu et al's polypeptide and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than Liu et al's polypeptide.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
September 29, 2009